The Honorable Lauren King

UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF WASHINGTON
AT SEATTLE

PREMERA BLUE CROSS,

Plaintiff,

v.

GS LABS, LLC, a Delaware limited liability company,

Defendant.

Case No. 2:21-cv-01399-LK

DEFENDANT GS LABS, LLC'S MOTION TO DISMISS COMPLAINT

NOTE ON MOTION CALENDAR: APRIL 1, 2022

ORAL ARGUMENT REQUESTED

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I. INTRODUCTION

In response to the coronavirus pandemic and unprecedented national public health emergency, Defendant GS Labs, LLC ("GS Labs") answered the federal government's call and invested millions of dollars to develop COVID-19 testing sites in communities in need across the country. GS Labs did so in reliance on payment and immunity protections that the federal government expressly provided to laboratories, pharmacies, and other providers of critically needed COVID-19 countermeasures, such as testing and vaccines. To date, GS Labs has tested over 363,000 individuals at its Washington testing sites and identified over 50,000 positive cases—helping to reduce the spread of the virus among these individuals and untold others who potentially would have come into contact with them.

Contrary to GS Labs' remarkable efforts to counteract the pandemic, Plaintiff Premera Blue Cross ("Premera") brings this action hoping to avoid its clear obligation to pay for the tens of millions of dollars of tests that GS Labs undisputedly performed—tests that diagnosed tens of thousands of Washingtonians with COVID-19. At bottom, Premera's suit undermines Congress's intent to encourage and protect providers such as GS Labs in delivering countermeasures (such as diagnostic COVID-19 testing) that were essential to curbing the pandemic.

Under the Families First Coronavirus Response Act ("FFCRA"), Pub. L. No. 116-127 (2020), and the Coronavirus Aid, Relief, and Economic Security Act ("CARES Act"), Pub. L. No. 116-136 (2020), Premera simply does not have the choice not to pay or the ability to set prices as it chooses. Federal law is unambiguous: insurers are required to cover payment for all COVID-19 diagnostic testing without any cost-sharing with patients. Federal law also clearly provides that there are two ways in which claims for COVID-19 testing may be billed to insurers: (1) pre-negotiated rates between the provider and the insurer ***or*** (2) the "cash prices" that are posted by the provider for "out-of-pocket" payment. It is undisputed—Premera did not have negotiated rates with GS Labs. Thus, Premera is obligated under federal law to pay the "cash prices" posted publicly by GS Labs. Premera's lawsuit seeks to skirt that obligation.

Rather than pay what it owes for the COVID-19 testing that GS Labs performed, Premera manufactured claims to try to pay a lower price than the law requires. Premera contends that despite the

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clear federal mandate to provide coverage, it should be permitted to exclude tens of thousands of claims for diagnostic COVID-19 testing on the grounds that (1) GS Labs' use of multiple tests in accordance with CDC and expert guidelines are somehow not medically necessary; (2) the "cash prices" posted by GS Labs are unfair and deceptive because GS Labs offers hardship discounts to eligible patients in need; and (3) certain tests were administered in alleged violation of plan rules. While none of these allegations have any merit, the Court need not even reach them because federal law is clear that as a "covered person" administering a "covered countermeasure" (diagnostic testing), GS Labs is ***immune*** from suit under the federal Public Readiness and Emergency Preparedness Act, 42 U.S.C.A. sections 247d-6d, 247d-6e ("PREP Act"). As courts have recognized, the scope of PREP Act immunity is "broad" and "sweeping," and this immunity covers "all claims for loss" relating to the administration of covered countermeasures.

Though it was founded only two months into the pandemic, GS Labs quickly scaled to provide diagnostic testing and services in the fight against COVID-19. In compliance with federal guidance, GS Labs developed multiple testing sites staffed by nurses and offering same-day appointment availability in Iowa, Minnesota, Nebraska, Oregon, Washington, and others; states where many residents lacked sufficient access to other COVID-19 diagnostic testing providers. It is estimated that each positive test that GS Labs returns at one of its testing sites can prevent one to two other individuals from contracting COVID-19, helping slow the virus' spread in the community. This Court can and should decide now, as a matter of federal law, that GS Labs, as a provider of a "covered countermeasure" is immune from suit by Premera so it can continue to focus on providing COVID-19 testing services to combat this pandemic.

Dismissal on the basis of this immunity is necessary because it strikes at the heart of the PREP Act: ***"the PREP Act exists, in part, to remove legal uncertainty and risk."*** Advisory Opinion 20-04 at 1. Allowing Premera's suit to go forward would significantly discourage providers of COVID-19 testing and other countermeasures. Not only would they now be unable to rely on PREP Act immunity protections from liability, but they would be forced to litigate to recover payments for which the federal government has already recognized insurers such as Premera are responsible. The inability to timely

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recover required payments from insurers additionally threatens GS Labs (and other testing providers) from continuing to offer needed countermeasures during the pandemic and runs counter to the federal policies intended to promote these efforts.

Even if this Court does not find that the PREP Act bars this litigation, Premera's claims fail for the additional reasons that (1) federal law expressly authorizes billing insurers at the "cash price" posted by the provider; (2) Washington's Consumer Protection Act does not recognize "price gouging" as an unfair or deceptive trade practice; and (3) the ERISA claim fails to implicate Premera's role as a plan fiduciary or concrete harm to the plan.

GS Labs respectfully requests that this Court dismiss this action with prejudice in its entirety.

II. RELEVANT FACTUAL BACKGROUND

A. The Parties

GS Labs is a laboratory startup founded in January 2020 that provides COVID-19 testing throughout various sites in Iowa, Minnesota, Nebraska, Oregon, and Washington. (Compl. ¶¶ 2, 38.) Premera is an administrator for self-funded insurance plans throughout Washington State. (*Id.* ¶ 3.)

B. Congress Passed COVID-19 Relief Legislation to Promote Widespread Testing and Prevention Measures

On March 18, 2020, in response to the coronavirus pandemic and the unprecedented public health crisis, the federal government passed the first piece of COVID-19 legislation, the Families First Coronavirus Response Act ("FFCRA"), Pub. L. No. 116-127 (2020), which provided, among other things, expanded nutrition assistance, paid sick leave, enhanced unemployment insurance coverage, free coronavirus testing and coverage requirements, and increased federal Medicaid funding. Section 6001 of the FFCRA was written to generally require group health plans and health insurance issuers to provide coverage for certain services related to COVID-19 testing. Under the FFCRA, plans and issuers, like Premera, must provide this coverage without imposing any cost-sharing requirements (including deductibles, co-payments, and coinsurance), prior authorization, or medical management.

On March 27, 2020, the second phase of coronavirus legislation was signed into law: the Coronavirus Aid, Relief, and Economic Security Act ("CARES Act"), Pub. L. No. 116-136 (2020).

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Section 3202 of the CARES Act expanded upon the coverage requirements of the FFCRA and requires plans and issuers providing coverage for COVID-19 testing to reimburse the provider of diagnostic testing at an amount that equals the rate the plan and provider have negotiated or, if the plan or issuer does not have a negotiated rate with the provider, the "cash price" for such service that is listed by the provider on a public website.

Paramount among Congress's concerns in passing both the CARES Act and the FFCRA was to ensure individuals have access to ***free*** testing, particularly as areas were quickly becoming inundated with COVID-19 cases. Indeed, in April 2020, Representative Jim McGovern (D-MA) testified in the legislative record that in the early days of the pandemic "***lack of available testing is the number one stumbling block in America***." 166 Cong. Rec. H1907-07, H1908 (Apr. 23, 2020) (emphasis added). Likewise, Senator Chris Van Hollen (D-MD) similarly emphasized the importance of increasing individual access to free testing for Americans, testifying that in passing the FFCRA, the federal government "***made sure that testing was free because we don't want any American to say: I am not going to get tested even though I feel like I might have the symptoms. I am not going to get tested because I can't afford it.*** It is putting both themselves and others in the community at risk. So we said we have to make sure these tests are free." 166 Cong. Rec. S2022-04, S2057 (Mar. 25, 2020) (emphasis added).

C. GS Labs Responded to the COVID-19 Public Health Emergency

Spurred by the lack of access to COVID-19 testing, GS Labs began opening COVID-19 testing sites nationally. By December 2020, GS Labs began providing COVID-19 diagnostic testing services in Washington. GS Labs operates testing sites in the cities of Federal Way, Lynnwood, Bellevue, and Vancouver.[1] (Compl. ¶ 38.) Each testing site serves high volumes of patients with same-day appointments, when capacity allows, and is capable of accommodating as many as 1,000 patients a day. (*Id.* ¶ 40.)

[1] In response to demand for its services, GS Labs has opened a testing site in Seattle (Northgate) since the filing of this complaint.

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The diagnostic services GS Labs offers include COVID-19 antigen testing, COVID-19 PCR testing (both singular and in panels for other respiratory illnesses), and COVID-19 antibody testing. (*Id.* ¶¶ 42(a)–(c).) GS Labs requires that insured patients check a box stating, "I acknowledge that I am seeking a diagnostic test," and includes a disclaimer that states: "GS Labs only accepts insurance patients who are seeking testing for diagnostic purposes. Patients must be experiencing Covid-19 symptoms or have had a potential exposure to Covid-19 to qualify for a medically necessary diagnostic test." (*Id.* ¶¶ 59-60.). This disclaimer goes beyond what the CARES Act requires—the CARES Act/FFCRA make it clear that health plans cannot condition coverage on exposure or symptoms.

As required under the CARES Act and the FFCRA, GS Labs posted "cash prices" on its website for COVID-19 testing as follows during the period relevant to Premera's complaint:

Test	GS Labs' Posted Rate
COVID-19 Rapid Antibody	$380
COVID-19 Rapid Antigen	$380
COVID-19 PCR	$385
Respiratory PCR Panel (incl. COVID-19)	$979

(*Id.* ¶ 77.) GS Labs' original cash prices, which were on par with more than 20% of other labs in the United States, reflected its need to recoup its initial investment in setting up its testing infrastructure. GS Labs has since changed its cash prices to account for the changing market and the recoupment of its initial investment.

D. GS Labs Offers Discounts to Qualified Patients Seeking Diagnostic Testing

As regulators contemplated in the explanation of the meaning of "cash price," *see infra* Part I.A.2.c, GS Labs also offers discounts of up to 70% of its cash price to qualified low-income patients who choose to pay "out-of-pocket" or do not have insurance. (Compl. ¶¶ 84–87.)

E. Premera Refuses to Pay for Testing Services GS Labs Provided to Tens of Thousands of Washingtonians

Since February 2021, GS Labs has conducted tens of thousands of tests for Washingtonians, for which it submitted over 80,000 claims to Premera in excess of $26 million. (*Id.* ¶ 98.) Premera

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objected to these claims on three primary grounds: (1) the medical necessity of combined antibody, antigen, and/or PCR testing, along with other respiratory panels; (2) "cash price" pricing when GS Labs offered hardship discounts; and (3) the tests were allegedly faulty, and/or "not covered by Premera's policies." (*Id.* ¶¶ 100–107.) To date, Premera has paid only $10,000 toward GS Labs' COVID-19 testing claims[2], though GS Labs has continued to provide care to Premera's plan beneficiaries. (*Id.* ¶ 111.) In addition to refusing payment for the 80,000 claims, Premera alleges that it "did not owe and should not have paid some (or all) of [the $10,000]," due to alleged misconduct by GS Labs. (*Id.*)

F. Premera's Action Against GS Labs

GS Labs provided Premera with notice of its non-payment of claims in violation of the CARES Act and the FFCRA in March 2021. Without advance notice, Premera filed this lawsuit in October 2021 asserting three causes of action: (1) violation of the Washington Consumer Protection Act ("CPA"); (2) ERISA section 502(a)(3) and 28 U.S.C. sections 2201, 2202; and (3) declaratory relief. GS Labs denies that any of Premera's claims have merit and moves to dismiss on the grounds set forth below. To the extent this matter is not dismissed in its entirety, GS Labs reserves all rights to assert counter-claims against Premera, including for violation of the CPA for failing to issue required reimbursements under the CARES Act and the FFCRA, as well as for issuing false, misleading, and predatory billing statements to GS Labs' patients (and beneficiaries of Premera's ASO plans) for diagnostic COVID-19 testing claims that are required by federal law to be paid by Premera, for violations of the Sherman Act, and for unjust enrichment.

III. LEGAL STANDARD

Dismissal under Rule 12(b)(6) is appropriate when the complaint lacks a cognizable legal theory or sufficient facts to support a cognizable legal theory. *Mendiondo v. Centinela Hosp. Med. Ctr.*, 521 F.3d 1097, 1104 (9th Cir. 2008). A plaintiff's complaint must allege facts to state a claim for relief that is plausible on its face. *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). Rule 12(b)(6) dismissal with prejudice is proper where a complaint's claims are barred by federal preemption. *See, e.g., Bennett v. T-*

[2] Since filing its Complaint, Premera has paid another $85,000 in claims for certain self-insured plans for which it acts as plan administrator.

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Mobile USA, Inc., 597 F. Supp. 2d 1050, 1053 (N.D. Cal. 2008) ("Therefore, Plaintiff's claims are conflict preempted and fail to state a claim upon which relief can be granted."). When amendment would be futile, dismissal with prejudice is likewise appropriate. *Dumas v. Kipp*, 90 F.3d 386, 393 (9th Cir. 1996).

IV. THE COURT SHOULD DISMISS THE ENTIRE COMPLAINT WITH PREJUDICE

A. Premera's Claims Are Barred by the PREP Act, the CARES Act, and the FFCRA.

Premera's claims fail as a matter of law—and are incurably flawed—because they are barred by federal law under (1) the federal immunity afforded to "covered persons" for administering "covered countermeasures" pursuant to the PREP Act, 42 U.S.C. § 247d-6d(a)(2)(B) (2020); and (2) because the conduct complained of—submission of claims for reimbursement at "cash prices" from Premera—is expressly required under the CARES Act and the FFCRA.

1. GS Labs is Immune from Suit and Liability Under the PREP Act.

At the outset, Premera's claims are barred as a matter of law because they have a "causal relationship" with the administration of a covered countermeasure immunized from liability under the PREP Act. *Id.* Because the PREP Act immunizes "covered" entities like GS Labs that provide approved "countermeasures," including COVID-19 testing, from suit during national crises, Premera's claims must be dismissed. *See Maglioli v. Alliance HC Holdings LLC*, 16 F.4th 393, 401 (3d Cir. 2021) ("A covered person enjoys immunity from all claims arising under federal or state law that relate to the use of a covered countermeasure.") (citing 42 U.S.C. § 247d-6d(a)(1)).

A brief factual background of the PREP Act is helpful to understand why Premera's claims fall squarely within the scope of PREP Act immunity. In 2005, Congress passed the Public Readiness and Emergency Preparedness Act ("PREP Act"), 42 U.S.C. §§ 247d-6d, 247d-6e. The PREP Act protects certain "covered persons"—such as laboratories and drug manufacturers—from "claims for loss" during a public-health emergency to ensure that the administration of covered countermeasures to the immediate crisis are prioritized without the distraction or imminent risk of litigation. A "covered person" is broadly defined as "a person or entity that is . . . a distributor . . .; a program planner . . . ; a

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qualified person who prescribed, administered; or dispensed such countermeasure, or an official, agent, or employee of such a person or entity." 42 U.S.C. §§ 247d-6d(i)(2),(5) (2020).

Immunity under the PREP Act arises once the Secretary of the Department of Health and Human Services ("HHS") invokes a public-health emergency. As the Third Circuit explained in *Maglioli*:

> The PREP Act protects certain covered individuals—such as pharmacies and drug manufacturers—from lawsuits during a public-health emergency. The Act lies dormant until invoked by the Secretary of the Department of Health and Human Services ("HHS"). If the Secretary deems a health threat a public-health emergency, he may publish a declaration in the Federal Register recommending certain "covered countermeasures." ***When the Secretary makes such a declaration, the covered individuals become immune from suit and liability from claims related to the administration of a covered countermeasure***.

16 F.4th at 400-01 (emphasis added) (citing U.S.C. §§ 247d-6d(a)(1) & (b)(1)).

That is precisely what is at issue here. On March 17, 2020, the HHS Secretary issued a Declaration under the PREP Act, effective February 4, 2020, making effective a broad immunity for the use of a range of medical products in the fight against COVID-19. 85 Fed. Reg. 15198, 15202 (2020); *see also* Pub. L. No. 109-148, 119 Stat 2680 (2015), Public Health Service Act § 319F-3, 42 U.S.C § 247d-6d and 42 U.S.C. § 247d-6e (2020). The March 17, 2020 declaration created expanded categories of broadly defined "covered countermeasures" eligible for immunity under the PREP Act as:

> Covered Countermeasures are any antiviral, any other drug, ***any biologic, any diagnostic, any other device***, or any vaccine, ***used to treat, diagnose, cure, prevent, or mitigate COVID-19, or the transmission of SARS-CoV-2 or a virus mutating therefrom***, or any device used in the administration of any such product, and all components and constituent materials of any such product.

85 Fed. Reg. 15198, 15202 (2020) (emphasis added).

As courts have recognized, the scope of PREP Act immunity that the HHS Secretary's Declaration triggered is "broad" and "sweeping." *See Maglioli*, 16 F.4th at 401 ("The scope of immunity is broad. Covered persons are immune from 'any claim for loss that has a causal relationship with the administration to or use by an individual of a covered countermeasure.'") (quoting 42 U.S.C. § 247d-6d(a)(2)(B)); *Garcia v. Welltower OpCo Grp. LLC*, 522 F. Supp. 3d 734, 739 (C.D. Cal. 2021) ("Once the Secretary has issued a declaration, the PREP Act provides sweeping immunity for certain

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claims against certain covered individuals[.]"). The Secretary controls the scope of immunity through the Declaration and amendments, within the confines of the PREP Act.[3] Covered persons are immune from "any claim for loss that has a causal relationship with the administration to or use by an individual of a covered countermeasure." 42 U.S.C. § 247d-6d(a)(2)(B) (2020). That includes claims relating to "the design, development, clinical testing or investigation, manufacture, labeling, distribution, formulation, packaging, marketing, promotion, sale, purchase, donation, dispensing, prescribing, administration, licensing, or use of such countermeasure." *Id.*[4] *See also Maney v. Brown*, 2022 WL 377900, at *2 (D. Or. Feb. 8, 2022) ("Courts analyzing the scope of the PREP Act have consistently held that the PREP Act's immunity provision applies to those who administer or use covered countermeasures[.]").

Parker v. St. Lawrence County Pub. Health Dep't, 102 A.D.3d 140 (N.Y. App. 2012) is instructive in defining the scope of PREP Act immunity. *Parker* arose out of the H1N1 influenza crisis and involved claims asserted by parents of a child who sued a county health department, claiming that administration of a flu vaccine to their child without the parents' consent constituted negligence and resulted in a battery upon her. *Id.* Citing the PREP Act, the *Parker* court determined that all of the claims were preempted:

> Considering the breadth of the preemption clause together with the sweeping language of the statute's immunity provision, we conclude that Congress intended to preempt all state law tort claims arising from the administration of covered countermeasures by a qualified person pursuant to a declaration by the Secretary, including one based upon a defendant's failure to obtain consent.

Id. at 143-44; *see also id.* at 144 (presuming that Congress recognized "consequences" in "administering a vaccination program" but "determined that such potential tort liability must give way to the need to

[3] The Secretary has since amended the declaration ten times. *See* 87 Fed. Reg. 5, 982 (2022) ("Tenth Amendment to Declaration Under the PREP Act for Medical Countermeasures Against COVID-19"). HHS has also issued many advisory opinions and guidance letters on various issues related to the declaration.

[4] Congress did not leave those injured by covered countermeasures without recourse. The Act establishes a fund to compensate "eligible individuals for covered injuries directly caused by the administration or use of a covered countermeasure." 42 U.S.C. § 247d-6e(a). The Secretary has broad authority to issue regulations determining who and what types of injuries qualify for compensation under the fund. *Id.* § 247d-6e(b)(4)–(5).

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promptly and efficiently respond to a pandemic or other public health emergency" with PREP Act immunity).

Additionally, the breadth of PREP Act immunity is not limited to tort, product defect, and personal injury claims, but rather such claims serve as a starting point. The PREP Act provides immunity for "all claims for loss" relating to the administration of a covered countermeasure and such "claims for loss" expressly include "loss of or damage to property," including but not limited to "business interruption loss." 42 U.S.C. §§ 247d-6d(a)(1) & (a)(2)(A)(iv). As congressional analysts have recognized, the "minimum" scope of PREP Act immunity encompasses "most state law tort, medical malpractice, and wrongful death claims arising from the administration of covered countermeasures," but this is not the maximum scope given the Act's broad sweep. *See* Kevin J. Hickey (Legislative Attorney), Congressional Research Service, "The PREP Act and COVID-19: Limiting Liability for Medical Countermeasures," *available at* https://crsreports.congress.gov/product/pdf/LSB/LSB10443. The PREP Act's sweeping immunity is consistent with Congress's recognition that "in the context of a public health emergency, immunizing certain persons and entities from liability was necessary to ensure that potentially life-saving countermeasures will be efficiently developed, deployed, and administered." *Id.*

HHS likewise has repeatedly emphasized the broad scope of PREP Act immunity, and the importance of providing immunity from claims to prevent the disruption of the delivery of covered countermeasures in this pandemic. Indeed, on October 22, 2020, as amended on October 23, 2020, HHS issued an advisory opinion reiterating the broad sweep of PREP Act immunity:

> ***The PREP Act exists, in part, to remove legal uncertainty and risk.*** When an individual or organization satisfies the requirements of the PREP Act and the Declaration, that "covered person" "shall be immune from suit and liability under Federal and State law with respect to all claims for loss caused by, arising out of, relating to, or resulting from the administration to or the use by an individual of a covered countermeasure."

Advisory Op. 20-04 on the PREP Act and the Secretary's Decl. Under the Act (Oct. 22, 2020) (emphasis added), as amended Oct. 23, 2020, *available at*

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https://www.hhs.gov/guidance/document/advisory-opinion-20-04-public-readiness-and-emergency-preparedness-act-and-secretarys.

"Indeed, when asked to interpret statutory language including the phrase 'relating to,' … [courts have] typically read the relevant text expansively." *Lamar, Archer & Cofrin, LLP v. Appling*, 138 S. Ct. 1752, 1760 (2018); *see also Morales v. Trans World Airlines, Inc.*, 504 U.S. 374, 378-90 (1992) (explaining that "'relating to'" has a "broad" ordinary meaning). To that end, courts considering immunity statutes that rest on analogous "arises out of or relates to" standards to those at issue under the PREP Act have applied that corresponding immunity broadly. *See, e.g.*, *King v. Nat'l Futures Ass'n.*, 189 F.3d 473, 475 (9th Cir. 1999) (applying statutory agency principles broadly to hold that statutory immunity under Securities & Exchange Act of 1934 granted "absolute immunity when acting under the aegis of authority delegated by Congress"); *Pani v. Empire Blue Cross Blue Shield*, 152 F.3d 67, 74 (2d Cir. 1998) ("We hold that a private insurance company acting as a fiscal intermediary or carrier on behalf of the United States in the administration of a Medicare program is entitled to *official immunity* for claims that arise out of the performance of its duty to investigate and report possible fraud"); *Young v. Bishop Est.*, 2009 WL 3763029, at *9 (D. Haw. Nov. 6, 2009) (judicial immunity bars claims that "relate to and arise out of [defendant's] performance of her duties as a judge" where defendant "exercised discretionary judgment in his capacity as a court-appointed master"). The reason for this broad approach to immunity naturally flows from its purpose, which is to protect those who take on highly discretionary and/or high-risk duties of significant importance from potential litigation risk, which would disrupt the orderly performance of those duties. *Id.*

Here, the case for GS Labs' immunity from suit is particularly compelling given that it was one of the few laboratories in the country that rose to provide testing and screening in the early days of the COVID-19 pandemic, before vaccines were even available. GS Labs has undisputedly provided COVID-19 testing services for tens of thousands of Premera insureds in Washington State and helped reduce the virus' transmissibility in the community. GS Labs' immunity necessarily flows from a straight-forward reading of the PREP Act, which prioritizes the performance of covered countermeasures during times of crisis over the threat of litigation such as this. "For PREP Act

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immunity to apply . . . Defendants must demonstrate that (1) they are covered persons; (2) Plaintiffs' claim is one for loss; and (3) the loss was caused by, arose out of, related to, or resulted from the administration to or use by an individual of a covered countermeasure." *Maney*, 2022 WL 377900, at *3. Here, GS Labs is a "covered person" pursuant to 42 U.S.C. § 247d-6d(i)(2),(5), as a laboratory administering COVID-19 testing; Premera's claims are for monetary loss; and Premera's claims arise from and relate to GS Labs' administration of COVID-19 testing to Premera's insureds. (Compl. ¶¶ 9–10.) "Per its express statutory terms, the PREP Act applies to the 'administration to or use of' a covered countermeasure[.]" *Maney*, 2022 WL 377900, at *3; *see also Estate of Maglioli v. Andover Subacute Rehab. Ctr. I*, 478 F. Supp. 3d 518, 532 (D.N.J. 2020) (recognizing administration of countermeasures as "activities that the PREP Act promotes by affording immunity"). Premera's lawsuit has a direct causal relationship with GS Labs' administration of COVID-19 testing, i.e., a "covered countermeasure," and must be dismissed, consistent with the statutory language of the PREP Act and the "broad" and "sweeping" immunity the Act provides to covered entities such as GS Labs that are delivering COVID-19 testing in response to HHS's declared public-health emergency.

2. The CARES Act and the FFCRA Require Premera to Cover GS Labs' "Cash Price" for Diagnostic COVID-19 Testing.

While this Court should dismiss all of Premera's claims outright because they are barred under the PREP Act, this is not the only federal law that requires dismissal of this action. Premera's claims fail on separate and independent grounds because they are preempted by the CARES Act, Pub. L. No. 116-136 section 3202(a)(2), and the FFCRA, Pub. L. No. 116-127 section 6001(a)(1)–(2). Specifically, Premera's claims are preempted because the CARES Act expressly authorizes GS Labs to charge Premera its "cash prices" for testing, and HHS has provided express guidance on what types of "cash prices" may be billed to insurers, like Premera, even where the provider offers discounts to patients.

a. Conflict Preemption Principles Apply.

It is blackletter law that Congress has the constitutional power to preempt state law, U.S. Const. Art. VI, cl. 2; *Gibbons v. Ogden*, 22 U.S. 1 (1824), and may do so either expressly—through clear statutory language—or implicitly. Under conflict preemption, Congress's intent to preempt state law is

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implied to the extent that federal law actually conflicts with any state law. *Whistler Invs., Inc. v. Depository Tr. & Clearing Corp.*, 539 F.3d 1159, 1164 (9th Cir. 2008) (citing *Hillsborough Cnty. v. Automated Med. Labs., Inc.*, 471 U.S. 707, 713 (1985)).

Conflict preemption analysis examines the federal statute as a whole to determine whether a party's compliance with both federal and state requirements is impossible or whether, in light of the federal statute's purpose and intended effects, state law poses an obstacle to the accomplishment of Congress's objectives. *Crosby v. Nat'l Foreign Trade Council*, 530 U.S. 363, 373 (2000). Conflict preemption applies where '"compliance with both federal and state regulations is a physical impossibility"' or where state law '"stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress."' *Ting v. AT&T*, 319 F.3d 1126, 1136 (9th Cir. 2003) (quoting *Florida Lime & Avocado Growers, Inc. v. Paul*, 373 U.S. 132, 142-43 (1963) and *Hines v. Davidowitz*, 312 U.S. 52, 67 (1941)). Conflicts that arise between federal and state law must be resolved in favor of federal law. *See* U.S. Const. Art. VI, cl. 2; *Maryland v. Louisiana*, 451 U.S. 725, 746-47 (1981). Here, conflict preemption impels dismissal of all of Premera's claims because the gravamen of Premera's complaint—that GS Labs charged Premera its "cash prices" for COVID-19 testing—is expressly authorized by federal law and Premera's state law claims frustrate the very purpose of that federal law.

b. The CARES Act and the FFCRA Expressly Require Premera to Pay GS Labs' "Cash Price" in the Absence of Negotiated Rates.

Recognizing the importance of widespread diagnostic testing to limit the spread of COVID-19, Congress passed the FFCRA, which mandates that group health plans and health insurance issuers provide coverage, without any cost-sharing or prior authorization, for diagnostic COVID-19 testing:

> (a) IN GENERAL.— A group health plan and a health insurance issuer offering group or individual health insurance coverage . . ***shall provide coverage, and shall not impose any cost sharing (including deductibles, copayments, and coinsurance) requirements or prior authorization or other medical management requirements, for the following items and services*** furnished during any portion of the emergency period defined in paragraph (1)(B) of section 1135(g) of the Social Security Act (42 U.S.C. 1320b–5(g)) beginning on or after the date of the enactment of this Act:

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> (1) ***In vitro diagnostic products*** *. . .* ***for the detection of SARS–CoV–2 or the diagnosis of the virus that causes COVID–19 that are approved, cleared, or authorized under section 510(k), 513, 515 or 564 of the Federal Food, Drug, and Cosmetic Act, and the administration of such in vitro diagnostic products***.
>
> (2) ***Items and services furnished to an individual during health care provider office visits*** (which term in this paragraph includes in-person visits and telehealth visits), urgent care center visits, and emergency room visits ***that result in an order for or administration of an in vitro diagnostic product described in paragraph (1), but only to the extent such items and services relate to the furnishing or administration of such product or to the evaluation of such individual for purposes of determining the need of such individual for such product***.

Pub. L. No. 116-127 § 6001(a)(1)–(2) (2020) (emphasis added).

Congress further expanded on the scope of that mandatory coverage under the CARES Act, which requires health plans and issuers to reimburse providers of diagnostic COVID-19 testing one of two possible ways: (1) either a ***pre-negotiated rate*** in existence before the public health emergency declaration; or (2) at the ***cash price*** listed by the provider, or as otherwise negotiated. Specifically, the CARES Act provides:

> REIMBURSEMENT RATES.—A group health plan or a health insurance issuer. . . shall reimburse the provider of the diagnostic testing as follows:
>
> (1) If the health plan or issuer has a negotiated rate with such provider in effect before the public health emergency declared under section 319 of the Public Health Service Act (42 U.S.C. 247d), such negotiated rate shall apply throughout the period of such declaration.
>
> (2) If the health plan or issuer does not have a negotiated rate with such provider, such plan or issuer shall reimburse the provider in an amount that equals the cash price for such service as listed by the provider on a public internet website, or such plan or issuer may negotiate a rate with such provider for less than such cash price.

Pub. L. No. 116–136 § 3202 (2020). Given that Premera does not allege (or have) any negotiated rates with GS Labs, (1) Premera was required under federal law to cover diagnostic COVID-19 testing, as set forth in Pub. L. No. 116-127 section 6001(a)(1)–(2); and (2) Premera is required to pay GS Labs its "cash price" for COVID-19 diagnostic testing, as defined under federal regulations. The Federal Register defines "cash price" as "the charge that applies to an individual who pays in cash (or cash equivalent) for a COVID-19 diagnostic test." 85 Fed. Reg. 71142, 71152 (2020).

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The legislative history of both the CARES Act and the FFCRA underscore that Congress was deeply concerned about incentivizing diagnostic testing providers and intentionally structured both government funding ***and*** legal coverage requirements to encourage wider access to testing. For example, Representative Kay Granger (R-TX) specifically testified in passing the FFCRA:

> [The FFCRA] builds off of last week's bill, where we expanded the availability of tests for the coronavirus to ensure that everyone who needs to be tested, gets tested.. . . ***We must ensure tests are administrated so that people know if they are infected. This is the only way we can stop the spread of this virus.***

166 Cong. Rec. H1675-09, H1687 (Mar. 13, 2020) (Rep. Granger) (emphasis added). Likewise, Representative Ilhan Omar (D-MN) testified: "We must vastly increase the number of tests and make sure that everyone presenting with mild cold or flu like symptoms is tested to accurately gauge the spread of COVID-19 in communities." 166 Cong. Rec. H1675-09, H1690 (Mar. 13, 2020) (Rep. Omar).

c. GS Labs' Offering of "Hardship Discounts" Does Not Invalidate its "Cash Prices."

In pronouncing the regulations, the federal government expressly contemplated that providers could provide discounted or charity rates "as charity care or in an effort to combat the public health crisis," and specifically advised that the posting of the "cash price" does not preclude the offering or issuance of discounts:

> We do not believe that posting a "cash price" should prevent a provider of a diagnostic test for COVID-19 from offering testing for free to individuals as charity care or in an effort to combat the public health crisis, rather, ***the "cash price" would be the maximum charge that may apply to a self-pay individual paying out-of-pocket***.

85 Fed. Reg. 71142, 71152 (2020) (emphasis added). Notably, neither regulators nor Congress have required providers to alter cash-price billing or claims for coverage of COVID-19 diagnostic services that have been rendered at a discount from the "cash price." *Id.*

But that is precisely the focus of Premera's complaint. Despite being a sophisticated insurer that knowingly chose to forego negotiating a discounted rate with GS Labs, Premera now contends it should nonetheless not have to pay for diagnostic testing because it does not agree with GS Labs' "cash prices." Specifically, Premera alleges that GS Labs engaged in the "unfair" trade practice of "[p]rice gouging . . .

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to charge far more than the fair market value of the testing performed" (Compl. ¶ 116(e)) and "[p]osting false and deceptive 'cash prices'" to mislead Premera as to the 'cash prices' it charges for COVID-19 testing in order to obtain higher payments from insurers," (*id.* ¶ 120(d)). *See also id.* ¶120(e). Premera argues that GS Labs' "cash prices" are a sham" (*id.* ¶ 7) because GS Labs "charges rates that are less than *one third* of those it has posted to its website" and by offering "every cash-pay patient a 'discount' of at least 70% on its 'cash prices,'" (*id.*); *see also id.* ¶¶ 76–97 ("GS Labs' False 'Cash Prices' for COVID-19 Testing"). Premera further complains that GS Labs' "cash prices" are unreasonable because they "exceed the reimbursement rates set by Medicare Administrative Contractors." (*Id.* ¶¶ 76–81.) Premera thus contends that "[b]ecause GS Labs charges all or virtually all cash-pay patients less than one third of its claimed 'cash price,'" that "GS Labs has failed to post its 'cash price' as that term is defined under the CARES Act." (*Id.* ¶ 92.)

This is simply not true in fact or in law. Even assuming *arguendo* that Premera's characterization of GS Labs' billing practices is correct (it is not), Premera still fails to plead a claim because neither Congress nor HHS administrators required a provider's "cash price" to mirror Medicare reimbursement rates, nor the price "actually charged" some segment of patients. Pub. L. No. 116-127 § 6001(a)(1)–(2) (2020). Quite the contrary, the regulations make clear that the "cash price," is simply the posted price that "an individual who pays in cash (or cash equivalent) [pays] for a COVID-19 diagnostic test." 85 Fed. Reg. 71142, 71152 (2020). The law, regulations, and regulatory commentary explain that the posting of a "cash price" should not and ***does not*** prohibit providers from providing discounts for charity care or other individuals given the public health crisis caused by the COVID-19 pandemic. ("We do not believe that posting a 'cash price' should prevent a provider of a diagnostic test for COVID-19 from offering testing for free to individuals as charity care or in an effort to combat the public health crisis. . . ."). *Id.* Because GS Labs' cash price complies with the express parameters set forth in the CARES Act and FFCRA, federal law preempts Premera's claims. *Ting*, 319 F.3d at 1136.

Ultimately, to allow Premera's claims to proceed would deny GS Labs the immunity protections and payment guarantees that Congress expressly provided in the PREP Act, CARES Act, and FFCRA, which GS Labs relied on in investing millions of dollars in developing testing sites across the country in

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response to the pandemic. Premera's failure to pay tens of millions of dollars of diagnostic testing claims threatens GS Labs' ability to continue providing critically needed COVID testing services. This very lawsuit—and the inevitable copycat cases that follow—discourages individuals and companies from delivering countermeasures in the face of a national public health emergency. Such litigation defies Congress's intent behind the immunity and preemption principles at issue here.

d. Premera's Allegations Regarding Medical Necessity Fail Because Federal Regulations Defer to Providers As to Appropriate Testing.

Premera's allegations that GS Labs violated the CPA by conducting medically unnecessary testing "to obtain higher payments from insurers" similarly are precluded under the CARES Act and the FFCRA. (Compl. ¶¶ 116(a)–(d); 120(a)–(c), (e).) To start, HHS recognizes that COVID-19 diagnostic testing is presumed to be medically appropriate: "When an individual seeks and receives a COVID-19 diagnostic test from a licensed or authorized health care provider, or when a licensed or authorized health care provider refers an individual for a COVID-19 diagnostic test, plans and issuers generally must assume that the receipt of the test reflects an 'individualized clinical assessment' and ***the test should be covered without cost sharing, prior authorization, or other medical management requirements***." *See* FAQs About FFCRA and CARES Act Implementation Part 44 (Feb. 26, 2021), *available at* https://www.cms.gov/files/document/faqs-part-44.pdf (emphasis added).[5]

Again, Premera fundamentally misunderstands its coverage obligations under the FFCRA and CARES Act. As the FAQs to the FFCRA and the CARES Act make clear, the government has expressly declined to exclude the administration of antibody testing or other respiratory illness screening from coverage under the FFCRA and CARES Act. Pub. L. No. 116-127 § 6001(a)(2) (requiring coverage not only for COVID-19 diagnostic testing but for "[i]tems and services furnished to an individual during health care provider office visits . . . that result in an order for or administration of an in vitro diagnostic product described in paragraph (1).").[6] Applying these principles, the CDC

[5] The same guidance clarifies that when individuals receive COVID-19 testing at an authorized drive-through site, issuers "generally must assume that the receipt of the test reflects an 'individualized clinical assessment.'"

[6] See also, FAQs About Families First Coronavirus Response Act and Coronavirus Aid, Relief, and Economic Security Act Implementation, Part 42 (Apr.11, 2020), available at: https://www.cms.gov/files/document/FFCRA-Part-42-FAQs.pdf (["Q4. Do "in vitro diagnostic tests" described in section 6001(a)(1) of the FFCRA, as amended by section 3201 of the CARES Act,

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"strongly encourages clinicians to test for other causes of respiratory illness" and has advised that "if the individual's attending provider determines that other tests (e.g., influenza tests, blood tests, etc.) should be performed during a visit . . . to determine the need of such individual for COVID-19 diagnostic testing, and [the] visit results in an order for, or administration of COVID-19 diagnostic testing, ***the plan or issuer must provide coverage for the related tests under section 6001(a) of the FFCRA***." *See* FAQs About FFCRA and CARES Act Implementation Part 42 (Apr. 11, 2020), *available at* https://www.cms.gov/files/document/FFCRA-Part-42-FAQs.pdf (emphasis added).[7]

Because Premera's state law claims conflict with the plain language of the CARES Act and the FFCRA's requirements for coverage of COVID-19 diagnostic and related testing at "cash prices," Premera's claims must be dismissed under federal conflict preemption principles. *See, e.g.*, *Whistler*, 539 F.3d at 1167 (affirming finding of conflict preemption where state law claims would conflict with approved program authorized under federal law and regulations).

B. Premera Fails to State a Claim Under the CPA Based on Alleged Price Gouging.

Premera's CPA claim for alleged price gouging fails for the additional reason that Washington does not recognize "price gouging" as an unfair or deceptive trade practice under the CPA. (*Cf.* Compl. ¶¶ 7–16, 113, 116(e), 120(d), 120(e).)

"A claim under the CPA requires proof of five elements: '(1) [an] unfair or deceptive act or practice, (2) occurring in trade or commerce, (3) public interest impact, (4) injury to plaintiff in his or her business or property, [and] (5) causation.'" *Berkshire Hathaway Homestate Ins. Co. v. SQI, Inc.*, 132 F. Supp. 3d 1275, 1294 (W.D. Wash. 2015) (quoting *Hangman Ridge Training Stables, Inc. v. Safeco Title Ins. Co.*, 105 Wn.2d 778, 780 (1986)). To satisfy the first element, plaintiffs may allege

include serological tests for COVID-19? Yes. Serological tests for COVID-19 are used to detect antibodies against the SARS-CoV-2 virus, and are intended for use in the diagnosis of the disease or condition of having current or past infection with SARS-CoV-2, the virus which causes COVID-19. The Food and Drug Administration (FDA) currently believes such tests should not be used as the sole basis for diagnosis. FDA has advised the Departments that serological tests for COVID-19 meet the definition of an in vitro diagnostic product for the detection of SARS-CoV-2 or the diagnosis of COVID-19. Therefore, plans and issuers must provide coverage for a serological test for COVID-19 that otherwise meets the requirements of section 6001(a)(1) of the FFCRA, as amended by section 3201 of the CARES Act.")

[7] *See also* Centers for Disease Control, Lab Advisory: Updated Guidance on Testing for Persons for Coronavirus Disease 2019 (COVID-19), *available at* https://www.cdc.gov/csels/dls/locs/2020/updated_guidance_on_testing_persons_for_covid-19.html (last accessed March 10, 2022) ("Clinicians are strongly encouraged to test for other causes of respiratory illness as well (e.g., influenza).").

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facts constituting a "per se violation of statute, an act or practice that has the capacity to deceive substantial portions of the public, or an unfair or deceptive act or practice not regulated by statute but in violation of public interest." *Klem v. Wash. Mut. Bank*, 176 Wn.2d 771, 787 (2013). To determine when an act or practice that is not a per se statutory violation is nonetheless an unfair "violation of public interest," Washington courts look to the FTC Act, as interpreted by the federal courts and the FTC. *Id.*; *see also* RCW 19.86.920.

Here, both Premera's "unfair" and "deceptive" trade practice claims premised on GS Labs' alleged "price gouging" fail as a matter of law because (1) Washington courts have not recognized price gouging as either a per se unfair or deceptive trade practice under the CPA, (2) the price gouging allegations do not satisfy the FTC's unfairness test; and (3) Premera has failed to allege any duty to disclose discounts or any pricing other than the federally required posted "cash price."

1. Price Gouging is Not a Per Se Unfair or Deceptive Trade Practice Under the CPA.

The pricing conduct Premera alleges is not per se unfair because no Washington statute prohibits it. "A per se unfair trade practice exists when a statute which has been declared by the Legislature to constitute an unfair or deceptive act in trade or commerce has been violated." *Hangman Ridge*, 105 Wn.2d at 786. Crucially, "the Legislature, not [the] court, is the appropriate body to [deem] a statutory violation to be a per se unfair trade practice." *Id.* at 787. Federal courts in Washington consistently reject per se claims under the CPA where the plaintiff does not identify a Washington statute addressing the alleged conduct. *See, e.g.*, *Castillo v. United Rentals, Inc.*, 2018 WL 1382597, at *8 (W.D. Wash. Mar. 19, 2018) ("[C]ourts after *Klem* have continued to recognize a per se violation only when a statute that has been declared by the legislature to constitute an unfair or deceptive act in trade or commerce has been violated.") (quotation marks & citation omitted); *Minnick v. Clearwire US, LLC*, 683 F. Supp. 2d 1179, 1186 (W.D. Wash. 2010) (dismissing CPA claim alleging that early termination fees were "per se unfair . . . under well-established, long-standing common law principles" because plaintiffs failed to "identif[y] a Legislatively recognized per se unfair practice").

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To the extent it is sufficiently alleged at all, Premera's nebulously pleaded price-gouging standard (referencing Medicare reimbursement rates or the potentially discounted price offered to qualifying patients) is not a "[l]egislatively-recognized per se unfair practice that would state a claim and, as such, the claim is incompatible with CPA jurisprudence." *Minnick*, 683 F. Supp. 2d at 1186.

2. The Price Gouging Allegations Do Not Satisfy the FTC's Unfairness Test.

The FTC itself has recognized that the FTC Act does not address price gouging. *See FTC v. Lundbeck, Inc.*, 2010 WL 3810015, at *4 n.3 (D. Minn. Aug. 31, 2010) (noting FTC argument that "[t]here is no U.S. law against price gouging"). Indeed, the FTC has never enforced the FTC Act in the price-gouging context. *See Gutierrez v. Bean*, 2006 WL 4117064, at *3 (D.N.M. Dec. 13, 2006) (court "unable to find any evidence of a claim for price 'gauging' or 'gouging' under federal law"). Applying the FTC test, Washington courts consider the following criteria when determining whether a practice or act is "unfair":

> (1) whether the practice, without necessarily having been previously considered unlawful, offends public policy as it has been established by statutes, the common law or otherwise—whether, in other words, it is within at least the penumbra of some common-law, statutory, or other established concept of unfairness; (2) whether it is immoral, unethical, oppressive, or unscrupulous; (3) whether it causes substantial injury to consumers (or competitors or other businessmen).

Magney v. Lincoln Mut. Sav. Bank, 34 Wn. App. 45, 57 (1983) (declining to treat due on-sale clauses as unfair where they did not offend any independent statute and have previously been upheld) (citing *FTC v. Sperry & Hutchinson Co.*, 405 U.S. 233, 244 n.5 (1972)).

Here, GS Labs priced its testing services in compliance with federal law, including to the extent it offered discounts to eligible and needy patients; where GS Labs' pricing was rendered in express compliance with federal law, Premera cannot show that GS Labs' pricing offends public policy, has otherwise been declared unlawful, or is otherwise unethical, oppressive, or unscrupulous. *Magney*, 34 Wn. App. at 57. Nor can Premera salvage its CPA claim by alleging that GS Labs' "cash prices" were deceptive trade practices undertaken "to obtain higher payments from insurers" or otherwise "false claims" because those "cash prices" were posted in compliance with federal law. Indeed, GS Labs was entitled to bill Premera at the "cash price" rate and was not otherwise under any duty to bill Premera at

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discounted rates, particularly given that Premera could have—but chose not to—negotiate with GS Labs for alternative rates.

For all the reasons discussed in Part IV.A.2, GS Labs did not affirmatively misrepresent its "cash prices" because its "cash prices" were the prices it offered to out-of-pocket patients, as authorized expressly by the CARES Act, regardless of whether it offered discounts to a narrower subset of qualifying patients. To the extent Premera's CPA claim is premised on GS Labs' purported omission of the hardship discounts it made available to eligible patients in need, Premera's claim fails because it has not and cannot allege that GS Labs had any duty to disclose its discounted hardship prices to Premera, on claims or otherwise. *See Nguyen v. Doak Homes, Inc.*, 140 Wn. App. 726, 734 (2007) (affirming dismissal of CPA claim for fraudulent omission where plaintiff failed to show duty).[8]

C. Premera Fails to State a Claim under ERISA Section 502(a)(3).

Premera's ERISA section 502(a)(3) claim is merely a dispute with a provider disguised as an ERISA section 502(a)(3) claim (presumably to preserve federal jurisdiction), and fails on multiple independent grounds. Premera purports to assert an ERISA section 502(a)(3) claim, which authorizes injunctive or other equitable relief for "any act or practice which violates any provision of [ERISA subchapter I] or the terms of the plan." 29 U.S.C. § 1132(a)(3) (2014). Premera contends that GS Labs violated ERISA by "submit[ing] false and misleading insurance claims to Premera's ERISA plans seeking reimbursement for medically unnecessary, inappropriate, and unauthorized testing, at exorbitant prices." (Compl. ¶ 134.) Premera's catch-all ERISA claim under section 502(a)(3) fails because: (1) Premera's claim is not brought as a fiduciary in a representative capacity on behalf of the plan and (2) Premera fails to allege any right or benefit under ERISA impacted by GS Labs or otherwise allege a concrete harm to the plan.

1. Premera Lacks Standing to Bring an Action Under ERISA Section 502(a)(3)

Premera alleges ERISA fiduciary status as a claims administrator. (*Id.* ¶ 17.) As a claims administrator, Premera performs ministerial tasks and at times may on occasion exercise discretionary authority over an individual claim. Premera alleges that it is authorized to pursue recovery of benefit

[8] Nor has Premera offered to pay the hardship prices.

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payments on behalf of those individuals. (*Id.* ¶ 25). Premera alleges that it has standing to recover benefits on behalf of individual participants—a claim that would be brought under ERISA section 502(a)(1)(b). *Id*. However, there are no allegations of individual benefit denials or individual recovery contained in the complaint. Moreover, there are no allegations of a concrete injury to any participant sufficient for Premera to have Article III standing. *Thole v US Bank*, 140 S. Ct. 1615, 1619 (2020).

Premera fails to allege any benefits or recovery owed to any individual participant pursuant to its role as a claims administrator under ERISA section 502(a)(1)(B). Rather, Premera is seeking equitable relief under ERISA section 502(a)(3). Although individualized relief is permitted under 502(a)(3), Premera is not seeking individual relief but rather equitable relief on behalf of the plan. Premera, as the claims administrator, is not a fiduciary with standing to bring such a claim. "ERISA's definition of [fiduciary status] is functional." *Bd. of Trs. of Laborers Health & Welfare Tr. Fund for N. Cal. v. Kudsk Const., Inc.*, 2012 WL 5373371, at *6 (N.D. Cal. Oct. 4, 2012) (quoting *LoPresti v. Terwilliger*, 126 F.3d 34, 40 (2d Cir. 1997)). Thus, while Premera may have been a fiduciary with respect to one particular participant claim, Premera is not a fiduciary with respect to the plan as a whole.

2. Premera Fails to Allege any Concrete Harm to the Plan by GS Labs or Otherwise Tailor the Equitable Relief to the Alleged Harm to the Plan.

The gravamen of this lawsuit is ***not*** a participant claim for a benefit under the plan; rather, it is a dispute between the claims administrator and a provider over the provider's rate of reimbursement under CARES Act section 3202(a). ERISA is not implicated because Premera fails to identify any plan provision or any specific injury incurred by a participant when GS Labs submitted claims for reimbursement at "cash prices" expressly authorized by the CARES Act. Because Premera fails to allege how, if at all, GS Labs violated a purported duty to the ERISA plans administered by Premera, the ERISA claim fails as a matter of law.

Premera's section 502(a)(3) claim fails for the additional reason that Premera fails to allege any concrete harm to the plan, let alone tailor its requested relief to the alleged harm. To state a claim under ERISA section 502(a)(3), a plaintiff must allege a substantive violation of the plan or ERISA itself. *See* 29 U.S.C. § 1132(a)(3) (2014) (authorizing lawsuits to "enjoin any act or practice which violates any

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provision of this subchapter or the terms of the plan" or "to obtain other appropriate equitable relief . . . to redress such violations"); *see also Moore v. Am. Fed'n of Television & Radio Artists*, 216 F.3d 1236, 1247 (11th Cir. 2000) (affirming dismissal of section 502(a)(3) claim that "contains no allegation, within the four corners of that count, that the [defendant] violated a substantive provision of ERISA or the terms of the [plan]").

As already discussed, Premera does not identify any plan provision that ***GS Labs*** allegedly breached. Moreover, Premera fails to allege that GS Labs is a fiduciary to the plan for purposes of violations of ERISA section 404(a). Rather, Premera contends blithely that "GS Labs' practices are deceptive, unfair, and unlawful" and that "GS Labs has systematically submitted false and misleading insurance claims to Premera's ERISA plans seeking reimbursement for medically unnecessary, inappropriate, and unauthorized testing, at exorbitant prices." (Compl. ¶¶ 134–35.) Such threadbare allegations fail to sufficiently allege a concrete harm sufficient to withstand a pleadings challenge. *See Acosta v. Pac. Enters.*, 950 F.2d 611, 621 (9th Cir. 1991) ("In order to state a claim for self-dealing under ERISA, [plaintiff] must demonstrate that [defendant] actually used its power to deal with the assets of the plan for its own benefit or account.").

Further, Paragraph 132 alleges only that "[t]he ASO plans at issue in this litigation covered by ERISA include the following or substantially similar language: 'If Premera makes a payment in error on your behalf to you or a provider, and you are not eligible for all or a part of that payment, Premera has the right to recover payment, including deducting the amount paid [sic] mistake from future benefits.'" (Compl. ¶ 132.) This implicates Premera's rights vis-à-vis the plan participants, not GS Labs, which does not have a contract with Premera and is not a plan participant. Again, because Premera fails to allege any right or benefit impacted by GS Labs, the ERISA claim fails as a matter of law.

The relief sought in Paragraphs 137 and 138 underscores that the purported injunction sought under section 502(a)(3) has nothing to do with the plan term identified in Paragraph 132:

> Premera is entitled to a judgment declaring that GS Labs' practices, violate the terms of Premera's ERISA plans and are not payable and void.

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> Premera further seeks an order enjoining GS from continuing to submit false and misleading insurance claims to Premera's ERISA plans seeking reimbursement for medically unnecessary, inappropriate and unauthorized testing, at exorbitant prices.

(*Id.* ¶¶ 137–38.)

Because Premera fails to allege either concrete harm to the plan—or injunctive relief tailored to redress any violation of a plan provision or rule—Premera's section 502(a)(3) claim fails. *Moore*, 216 F.3d at 1247. Also, as previously indicated, Premera lacks ERISA standing as well as Article III standing to raise any such alleged claims.

V. CONCLUSION

For the foregoing reasons, GS Labs respectfully asks this Court to dismiss Premera's Complaint with prejudice.

DATED this 10th day of March, 2022.

Respectfully submitted,

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